DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

July 20, 2015

Sotera Wireless, Inc.
Eben Gordon
Regulatory Consultant
10020 Huennekens Street
San Diego, California 92121

Re: K142827
Trade/Device Name: ViSi Mobile Monitoring System, ViSi Mobile Chest Sensor
Regulation Number: 21 CFR 870.1025
Regulation Name: Arrhythmia Detector And Alarm (Including St-Segment Measurement And Alarm)
Regulatory Class: Class II
Product Code: MHX, DSL, DRT, DXN, DQA, FLL
Dated: June 10, 2015
Received: June 11, 2015

Dear Eben Gordon:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply

with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement on last page.

510(k) Number *(if known)*
K142827

Device Name
ViSi Mobile Monitoring System

Indications for Use *(Describe)*

The ViSi Mobile Monitoring System is intended for use by clinicians and medically qualified personnel for single or multi-parameter vital signs monitoring of adult patients (18 years or older). It is indicated for ECG (3 or 5 lead-wire), respiration rate, heart rate, noninvasive blood pressure (NIBP), continuous non-invasive blood pressure (cNIBP), non-invasive monitoring of functional oxygen saturation of arterial hemoglobin (SpO2), pulse rate, skin temperature, basic arrhythmia analysis (Ventricular Tachycardia, Ventricular Fibrillation, Asystole, Atrial Fibrillation/Atrial Flutter) and alarm in hospital-based facilities; including general medical-surgical floors, intermediate care floors, and emergency departments.

Continuous non-invasive blood pressure (cNIBP) measurements have not been evaluated on patients during ambulation.

The basic arrhythmia analysis feature is intended for use on patients 18 years of age and older. It has not been evaluated on pediatric patients or neonates.

The arrhythmia analysis feature is intended for use by healthcare professionals trained in the identification and treatment of arrhythmia events. Automated arrhythmia analysis is an adjunct to clinical assessment; clinician review of the analysis should precede any therapeutic intervention.

The ViSi Mobile Monitoring System may be used as standalone devices or networked to a ViSi Mobile Remote Viewer through wireless 802.11 communication.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(K) SUMMARY

K142827

Date prepared	July 7, 2015
Name	Sotera Wireless, Inc. 10020 Huennekens Street San Diego, CA 92121 T. 858.427.4620; F. 858.999.2487
Trade name	ViSi Mobile Monitoring System
Common name	Vital signs monitor
Regulation Name	Arrhythmia detector and alarm (including ST-segment measurement and alarm)
Classification number	21 CFR 870.1025
Product code	MHX, DSI, DRT, DXN, DQA, FLL
Regulatory class	II
Predicate devices	Automated ECG Analysis and Interpretation Analysis Software Library, K062282 (Clearance: 03/22/2007) Acuity Central Monitoring Station, K052160 (Clearance: 12/16/2005) ViSi Mobile Monitoring System; K122036 (Clearance: 8/15/2012) ViSi Mobile Monitoring System; K130709 (Clearance: 10/7/2013)
Description	The ViSi Mobile Monitoring System is a lightweight, body-worn vital signs monitor featuring a high resolution, full color touch screen display, with visual and audible alarms and alerts. The ViSi Mobile Monitor is designed to continuously non-invasively measure ECG, basic arrhythmias [including ventricular tachycardia, ventricular fibrillation, asystole, and atrial fibrillation/atrial flutter], heart rate, SpO2, blood pressure, pulse rate, respiration rate, and temperature. The ECG, SpO2, and Respiration waveforms are viewable on demand. The ViSi Mobile Monitoring System is capable of one-time and continuous NIBP measurements.
510(k) Number	K142827
Indications for use	The ViSi Mobile Monitoring System is intended for use by clinicians and medically qualified personnel for single or multi-parameter vital signs monitoring of adult patients (18 years or older). It is indicated for ECG (3 or 5 lead-wire), respiration rate, heart rate, noninvasive blood pressure (NIBP), continuous non-invasive blood pressure (cNIBP), non-invasive monitoring of functional oxygen saturation of arterial hemoglobin (SpO2), pulse rate, skin temperature, basic arrhythmia analysis (Ventricular Tachycardia, Ventricular Fibrillation, Asystole, Atrial Fibrillation/Atrial Flutter) and alarm in hospital-based facilities; including general medical-surgical floors, intermediate care floors, and emergency departments.

Continuous non-invasive blood pressure (cNIBP) measurements have not been evaluated on patients during ambulation.

The basic arrhythmia analysis feature is intended for use on patients 18 years of age and older. It has not been evaluated on pediatric patients or neonates.

The arrhythmia analysis feature is intended for use by healthcare professionals trained in the identification and treatment of arrhythmia events. Automated arrhythmia analysis is an adjunct to clinical assessment; clinician review of the analysis should precede any therapeutic intervention.

The ViSi Mobile Monitoring System may be used as standalone devices or networked to a ViSi Mobile Remote Viewer through wireless 802.11 communication.

Summary of substantial equivalence

The basic arrhythmia analysis is based on the same technology as the currently cleared Monebo Technologies, Inc Arrhythmia library (K062282), which has been adapted for real time analysis in the ViSi System. The ViSi Monitoring System's basic arrhythmia analysis has been validated by comparison to the AHA, MIT-BIH, CU, and NST databases as prescribed in ANSI/AAMI EC57: 2012. The QRS detection sensitivity of the ViSi System was comparable to the predicate device.

The safety and effectiveness of the design elements implemented into the ViSi System have been confirmed by compliance to Class II Special Controls Guidance Document: Arrhythmia Detector and Alarm (October 28, 2003).

The ViSi System's basic arrhythmia analysis and alarms incorporates two additional rhythm classifications, artifact and unclassified, to minimize false alarms. Artifact detection prevents noisy signals from being detected as beats, thus excluding those signals from rhythm detection. In this way, false positive ventricular fibrillation and asystole events are minimized. If the artifact condition persists for >30 seconds, an equipment technical alarm is triggered. If the algorithm cannot classify the current rhythm, the rhythm is labeled as unclassified. If the condition persists for >30 seconds, an equipment technical alarm is triggered. These differences do not raise new questions of either safety or effectiveness.

<u>Non-Clinical Testing</u>

The ViSi System has successfully undergone database and functional testing to demonstrate equivalence to the predicate devices. Verification and validation testing was identified to support the safety and effective of the ViSi System and were relied upon in the determination of substantial equivalence. These non-clinical tests included:

- Performance against databases for arrhythmia analysis as specified in ANSI/AAMI EC57
- Electrical safety testing per AAMI/ANSI ES60601-1:2005
- Electromagnetic compatibility testing per IEC 60601-1-2 3rd Edition including Radiated Emissions, Electrostatic Discharge, Radio Frequency

Electromagnetic Field Amplitude Modulated, Radio Frequency Common Mode, and Power Frequency Magnetic Field

- Alarm system testing per AAMI/ANSI/IEC 60601-1-8:2006
- ECG performance according to AAMI/ANSI/IEC 60601-2-27:2011

The ViSi System has been tested and found to comply with the Special Controls Guidance, meet ANSI/AAMI EC57 performance requirements, and comply with recognized consensus standards for medical devices providing adequate support of substantial equivalence to the predicates devices. The results of all the testing demonstrate that the ViSi System is as safe, as effective, and performs as well as or better than the predicate device.